UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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CollaGenex Pharmaceuticals, Inc.
et al.,

Plaintiffs,

MEMORANDUM
& ORDER

-against-

04CV4253(SLT)(VVP)

IVAX Corporation, et al.,

Defendants.
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TOWNES, U.S.D.J.

By order dated January 21, 2005, this Court referred this matter to Magistrate Judge Viktor Pohorelsky for a Report and Recommendation on the Plaintiffs' motions for a temporary restraining order and a preliminary injunction.

A district court judge may designate a magistrate to hear and determine certain motions pending before the Court and to submit to the Court proposed findings of fact and a recommendation as to the disposition of the motion. *See* 28 U.S.C. § 636(b)(1). Within ten days of service of the recommendation, any party may file written objections to the magistrate's report. *See id.* Upon *de novo* review of those portions of the record to which objections were made, the district court judge may affirm or reject the recommendations. *See id.* The Court is not required to review the factual or legal conclusions of the magistrate judge as to those portions of the report and recommendation to which no objections are addressed. *See Thomas v. Arn*, 474 U.S. 140, 150, 106 S. Ct. 466, 88 L. Ed. 2d 435 (1985).

Judge Pohorelsky has recommended that this Court deny the Plaintiffs' motions for a temporary restraining order and preliminary injunctive relief. Plaintiffs filed timely objection to

the magistrate's report and the defendants IVAX Corporation and IVAX Pharmaceuticals, Inc. filed a timely response in opposition to Plaintiffs' objections.

The Court has carefully reviewed all papers in connection with: (1) all submissions by the parties in support of and opposition to the grant of Plaintiffs' motions; (2) the transcript of the proceedings held before Judge Pohorelsky on January 31, 2005; and (3) the instant objections to the Report and Recommendation and response thereto. In addition, this Court reviewed additional submissions by the parties on the issue of irreparable harm and heard proof and futher argument regarding this issue on May 23, 2005.

Applying the *de novo* standard of review, the Court adopts and affirms the Report and Recommendation.

DISCUSSION

"A preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted." *Intel Corp. v. ULSI Sys. Tech. Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993). While "grant or denial of a preliminary injunction pursuant to 35 U.S.C. § 283 is within the discretion of the district court," *Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, 77 F.3d 1364, 1367 (Fed. Cir. 1996), the burden is always on the movant to make a clear showing of entitlement to such relief. *Intel*, 995 F.2d at 1568. To obtain preliminary injunctive relief, the movant must show four factors: (1) reasonable likelihood of success on the merits; (2) irreparable harm if preliminary injunction is not granted; (3) that the balance of hardships tips in its favor; and (4) the impact of the injunction on the public interest. *Reebok Int'l, Ltd. v. Baker*, 32 F.3d 1552, 1555 (Fed. Cir. 1994); *Hybritech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed. Cir. 1988).

Upon a patentee's failure to make a clear showing of any one of the four factors, a trial court may deny the motion. *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 973-4 (Fed. Cir. 1996).

Likelihood of Success on the Merits

To show a reasonable likelihood of success on the merits, the movant must show infringement and validity of the patent. *Reebok*, 32 F.3d at 1555. In his Report and Recommendation, Judge Pohorelsky concluded that the Plaintiffs failed to satisfy their burden of proving that either of the Defendants' non-infringing and invalidity arguments lack substantial merit. The Plaintiffs object and argue that the recommendation as to each issue is clearly erroneous. This Court agrees with the sound logic employed by Judge Pohorelsky and adopts the findings made and the analysis performed by him.

Serious issues are raised by the Defendants as to whether the Plaintiffs' claims fail under prior art or the doctrine of double patenting. It is premature on this incomplete record to make findings in that regard, but since the Plaintiffs have failed to meet their burden of establishing that these issues are lacking in merit, a preliminary injunction should not issue.

Irreparable Harm

Having failed at showing a likelihood of success on the merits, Plaintiffs are not entitled to the presumption of irreparable harm. *Eli Lilly and Co. v. American Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed Cir. 1996). Judge Pohorelsky determined that Plaintiffs failed to make a showing of irreparable harm based on the following factors: (1) "most of [the harms alleged] emanate from an expected sharp drop in revenue," which can be compensated with money damages, particularly when the defendant would be able to satisfy any judgment that may be entered against it; (2) loss of the opportunity to develop other drugs is insufficient to constitute

irreparable harm; (3) Plaintiffs failed to allege loss of a business; (4) Plaintiffs' decision to bargain away its rights to Mutual did not weigh in favor of Plaintiffs; and (5) Plaintiffs' failure to disclose in its January 20, 2005, SEC Form 8-K that its viability was in danger. (Report and Recommendation at 13-16.)

In their objections to Judge Pohorelsky's Report and Recommendation (the "Objections"), Plaintiffs ask the Court to consider that monetary damages do not preclude a finding of irreparable harm; that there is a short period of time remaining on the patent; that loss of research and development constitutes irreparable harm; and that the Court ignored a nonbinding opinion granting an injunction to CollaGenex on what it describes as "almost identical" circumstances.

Money Damages

Plaintiffs argue that Judge Pohorelsky determined there was no irreparable harm "solely on a determination that the alleged infringer can pay money damages." (Objections at 5.) However, Judge Pohorelsky found a lack of irreparable harm not only because Plaintiffs' damages are quantifiable, but also because Plaintiffs have not made a persuasive argument that CollaGenex will not recover from the harm that would result should the Court deny its request for an injunction. Quantifiable monetary damages on their own cannot constitute irreparable harm, *Eli Lilly*, 82 F.3d 1578, but Judge Pohorelsky found that Plaintiffs showed little more than potential monetary damages. His Report and Recommendation found Plaintiffs' arguments that CollaGenex would be in financial ruin if the injunction does not issue unconvincing, particularly in light of both its SEC filings and voluntarily bargained-for agreement with Mutual.

In its moving papers and accompanying affidavits from Brian Gallagher, former Chief Executive Officer ("CEO") of CollaGenex and Colin Stewart, current CEO, Plaintiffs repeat that in the absence of an injunction, CollaGenex faces the possibility of economic collapse. (Gallagher Decl. ¶ 49 (sales by Defendants "will cause immediate and irreparable injury to CollaGenex and threaten its viability"); Stewart Decl. ¶ 31, 41 (sales by Defendants "threaten[] its viability as a pharmaceutical company" and "would destroy the value of CollaGenex"); Pl. Mem. of Law in Support of Mot. for T.R.O. at 16 ("CollaGenex will lose its ability to continue as a viable pharmaceutical company."); Pl. Mem. of Law in Support Em. Mot. for Prelim. Inj. at 38 ("This scale of harm is not compensable by monetary damages alone because it represents the loss of a business."); *Id.* at 41 ("With Periostat® being CollaGenex's only major source of revenue, it would be unlikely to survive."))

Plaintiffs also argued that CollaGenex is a "one-product Company," *Id.* at 39, that "Collagenex cannot yet finance its research and development program from sources other than Periostat®," Stewart Decl. ¶ 6, and that "severely diminishing revenues [which would result without an injunction]...would force CollaGenex to abandon development work underway...including its work on treating acne, rosacea, and Kaposi's Sarcoma, and its plans to explore new indications and other technologies." *Id.* at ¶ 33.

Additional Submissions

Subsequent to Judge Pohorelsky's Report and Recommendation, the parties submitted additional evidence on the issue of irreparable harm. The letters and declarations submitted by the parties, and the exhibits attached thereto, negate Plaintiffs' allegation that CollaGenex would

suffer catastrophic loss and therefore be unable to develop other products if the injunction is not issued.

On May 16, 2005, Defendants submitted a copy of CollaGenex's April 22, 2005 letter to its shareholders. (Letter from Wepner to Court of 5/16/05.) In it, Plaintiffs opined that, in the absence of the injunction requested of this court, CollaGenex "anticipates that Periostat® will be subject to generic competition sometime during 2005, which will cause our sales of Periostat® and Mutual's branded version of Periostat® to decline significantly. When this occurs, we will execute plans to reduce our cost base. *None of these actions will affect our commitment to develop Oracea and our dermatology franchise.*" (Shapiro Decl. Ex. A at 3) (emphasis added).

On May 5, 2005, CollaGenex held a First Quarter 2005 Earnings Conference Call in which CEO Stewart stated: "we believe it is more likely than not that the generic form of Periostat® will be approved by the FDA and launched sometime in the near future." (*Id.* Ex. B at 2.) Stewart goes on to describe the actions taken by CollaGenex "to manage the impact of the launch which generic form [*sic*] of Periostat® will have on our business." (*Id.*) Included in these actions are the reduction of the level of inventories held by Plaintiffs' wholesale customers, and Plaintiffs' decision to write off some of its inventory. (*Id.*) Stewart concluded his prepared statement with the following: "We are...*well prepared* for an eventual entry [of generic competition] and remain very focused on the *significant* opportunity that lies ahead in dermatology." (*Id.* at 3) (emphases added).

Plaintiffs responded to Defendants' May 16 submission with a letter dated May 17, 2005, attaching an article from the Philadelphia Inquirer, a copy of CollaGenex's Form 8-K, filed on May 16, 2005 and the transcript of May 16, 2005 conference call held by CollaGenex "to

Announce Restructuring." (Letter from Sack to Court of 5/17/05, Exs. D-F.) Each document confirms CollaGenex's plan to cut 63 of 135 employees if the injunction was not ordered by May 20, 2005. (Letter from Sack to Court of 5/17/05, Exs. D–F.) The 8-K quoted Stewart as stating: "While we are clearly disappointed with the generic approval, we remain confident in our ability to build CollaGenex's dermatology franchise." (Letter from Sack to Court of 5/17/05, Ex. E at 5.) And, in the conference call, Stewart announced that "[f]or the past 18 months, we at CollaGenex have stressed our strategy of building CollaGenex into a more broadly based speciality pharmaceutical company initially concentrating on dermatology and launching products from our own development pipeline." (Letter from Sack to Court of 5/17/05, Ex. F at 2.) Stewart said this *after* announcing the layoffs and budget cuts that Collagenex, by this point, had already contemplated. (*See id.*)

Defendants submitted a letter pointing out Plaintiffs' failure to reconcile the statements made in their moving papers with those made to their shareholders and on their conference calls. (Letter from Mentlik to Court of 5/18/05.) With oral argument on this issue scheduled for May 23, 2005, Plaintiffs submitted an additional Declaration on Sunday May 22 at 11:23 p.m. (*See* Supplemental Stewart Decl.) In it, Stewart now says, *inter alia*, that "the confidence of CollaGenex's employees, customers, strategic partners and investors in CollaGenex's ability to continue as an innovative growing presence *in the dental market*" has been undermined. (*Id.* at ¶ 6) (emphasis added). Indeed, the irreparable harm alleged by CollaGenex, in this declaration, is largely related to its position in the dental market. (*Id.* at ¶ 12 ("In the *dental* area the following programs will be abandoned or postponed..."); ¶ 13 ("[I]f CollaGenex loses its established presence in the *dental* market..."); ¶ 14 ("Our strategic partners in the *dental* business...have also

voiced concerns that their relationships with CollaGenex may not be viable in light of the uncertainty surrounding the future of CollaGenex's *dental* business"); ¶19 (CollaGenex "would not be able to resurrect its *dental* business"); ¶ 20 ("With an injunction, CollaGenex... [will be able to] maintain the goodwill it has built as a pioneer in the *dental* market place."); ¶ 21 ("With an injunction, CollaGenex will also have the revenues to be able to continue the development of Periostat MR and successor IMPACS™ compounds that have shown promise in the *dental* area.")) (emphases added). Prior declarations and memoranda made no such distinction.

The Stewart declaration also alleged that the restructuring plan formulated by CollaGenex "contemplates abandonment or postponement of various research and development initiatives which previously have been disclosed as targeted for completion or significant progression in the period between now and mid-2007," Supplemental Stewart Decl. at ¶ 11, and that certain non-dental research and development projects would be impossible without Periostat® revenues, including "dry eye," Restoraderm™, COL-3, and IMPACS™. *Id.* at ¶¶ 15-18. Outside funding for COL-3, Plaintiffs argue, would become difficult to obtain in light of the "depressed level of CollaGenex share price," and "[s]trategic partners in the non-dental business have voiced their concerns that their relationships may need to be reviewed." (*Id.* at ¶¶ 16-17.)

Oral Argument

The Court scheduled an oral argument in order to direct the parties to address a limited number of documents bearing on the issue of irreparable harm: the CollaGenex April 22, 2005 Annual Report to its shareholders, the transcript of the May 5, 2005 conference call and the

exhibits attached to Plaintiffs' May 17, 2005 letter to the court.[1] (Transcript of 5/23/05 Oral Argument ("Tr.") at 4.)

Again, Plaintiffs focused on the distinction, absent prior to the Report and Recommendation, between loss of its entire business and loss of its dental business:

Plaintiffs' Counsel:	[B]y the time this Court finally decides with the assistance of a jury whether this patent is infringed and what the damages are, this company will have been irreparably harmed, even if it still exists. It won't exist, it won't be viable in the form in which it exists today, a dental company.
	[...]
The Court:	Let me ask you this. You are confusing me because you are saying on the one hand that they may be able to survive.
Plaintiffs' Counsel:	Yes, Your Honor.
The Court:	On the other hand that the viability of the company as it exists...
Plaintiffs' Counsel:	The viability of the company. Periostat® has always been known in the marketplace –
The Court:	But if it can be replaced with something else.
Plaintiffs' Counsel:	If it can be replaced with something else then they may survive, but their survival does not negate the irreparable harm they have suffered.

(Tr. 10-11.) Plaintiffs then argued that irreparable harm exists because of loss of market share, loss of employees, loss of opportunity to pursue dental products, loss of research and

[1] By no means are these the only documents considered by the Court in evaluating whether the Plaintiffs have made an adequate showing of irreparable harm. The Court has considered all of the memoranda, affidavits and declarations, letters and exhibits submitted by the parties and requested argument on certain documents produced after briefing of the motions for a T.R.O. and preliminary injunction.

development, loss of shareholder value, loss of reputation in the marketplace and loss of licensing revenues to SUNY.

The Court then asked Plaintiffs' counsel about the contingency plans stated in the documents at issue:

Plaintiffs' Counsel: What this company has said, Your Honor, is no more than this: With $36 million in the bank, if we suffer the devastating loss of our patented product, which cuts off irrevocably the last two years of our patent's life, we are not simply going to go out of business. We are going to take that $36 million and try to become a successful dermatology company.

The Court: That is not what has been argued here. What has been argued here is that the loss of profit from Periostat® will result in an inability to fund any other, including the dermatological.

Plaintiffs' Counsel: With respect, Your Honor, that statement Your Honor just made is absolutely correct with the single exception of the word "any other." The plaintiff has alleged...that many of the research and development and other research programs will have to be eliminated, and indeed, many have been eliminated within the last two weeks...The annual report concluded by saying that this is going to be an exciting new phase of the company's development, which I think, Your Honor, calls to mind the old curse, may you live in exciting times. I think it may be, but that doesn't mean that it is going to be pleasant for either CollaGenex or its investors.

(Tr. 13-14.) Plaintiffs did not say that it "is going to be pleasant" but *did* optimistically declare that "[n]one of these actions will affect our commitment to develop Oracea and our dermatology franchise," that CollaGenex is "*well prepared* for an eventual entry [of generic competition] and remain[s] very focused on the *significant opportunity* that lies ahead in dermatology;" and that CollaGenex has "a strong balance sheet;" "no debt" and "expect[s] to increase [its] dermatology sales force significantly in early 2006 for the Oracea launch." (Shapiro Decl. Ex A at 3; Ex. B at 3) (emphases added). Plaintiffs now ask the Court to read "exciting" as being ambiguous in the face of these positive statements.

On cross-examination, Stewart was presented with his declaration, submitted on January 20, 2005, in support of the instant motions, in which he declared, multiple times and under oath, that the viability of CollaGenex as a company was threatened by the prospect of generic competition with Periostat®. (Tr. 40-41.) When asked to reconcile the statements as to CollaGenex's overall viability with Plaintiffs' new argument that it is CollaGenex's dental business that was described as possibly ceasing to exist, the following colloquy ensued:

Defense Counsel: Again, no qualification [in your declaration] that you were only concerned about your dental business, you were talking about the whole company there, weren't you?

Stewart: Yes, I was talking about the whole company.

Defense Counsel: Again, despite the fact that you had plans to expand your business into the dermatology field and were in the throes of actually doing so, is that correct?

Stewart: Yes.

(Tr. 40-41.)

Defense counsel then asked about the statement in Stewart's declaration that development of "its current work on treating acne, rosacea, and sarcoma" would have to be abandoned in the absence of an injunction. (Tr. 41.) Stewart replied, "No. We have discontinued work on sarcoma. We said with regard to acne, we couldn't afford to develop that all the way through, without having Periostat®." (Tr. 41-42.) Therefore, the statement as to rosacea (the condition for which Plaintiffs are currently developing Oracea) is inaccurate and it remains funded.

Defense counsel moved on to the statements bearing on Plaintiffs' viability that were contained in the memoranda submitted in support of the instant motions:

Defense Counsel: Did you consider that perhaps counsel was overstating the potential harm to the company in those briefs?

Stewart: It didn't touch me at the time.

Defense Counsel: It didn't touch you at the time. Does it touch you know?

Stewart: Yes.

Defense Counsel: So you think it was overstated to the Court?

Stewart: It could be.

Defense Counsel: For example, when it was stated to the Court that the loss of revenue would lead to the destruction of CollaGenex as a viable small pharmaceutical company, at the time that didn't strike you but it does today, is that what you are saying?

Stewart: I still believe the viability of CollaGenex is threatened.

Defense Counsel: Can you show me where...in the submissions to the SEC, where in your call to investors, where in the letters to the shareholders you qualify any of your statements about the continued viability of the company as to them as you have done to the Court here?

Stewart: I made no statements to them about continued viability.

Defense Counsel: None at all...What you did was you told them we are continuing, we are selling, we are getting approvals, and we expect to do really well in the future. Isn't that what you told them?

Stewart: That is correct.

Defense Counsel: You testified in response to your counsel's questions that it is possible that you will be able to continue to survive. Could you show me where you told the investors you only thought it was possible as opposed to painting a picture for them and to the SEC that you will indeed survive?

Stewart: I have not.

Defense Counsel: You have not done that. But here in court it is only 'possible,' here in court the fate of CollaGenex is in the hands of the Court. It didn't strike you when these statements were made back in January that they were overstated, is that a fair summary?

Stewart: Yes.

(Tr. 42-43.)

On redirect, Stewart then testified that he does believe the viability of CollaGenex "may" be threatened in the absence of an injunction:

Stewart: We have no idea and no indication as to what the clinical results are in the two Oracea studies. We do not know whether the FDA will approve the drug on the basis of the documents we submit. We don't know how long it will take the FDA to do their review. We have made an estimate that it would be 12 months. That it may be 18 months or longer. All of these steps are unknown to us.

The Court: But don't you – I'm sorry. The concern to me as I sit here when I am reading something else on the page...There is a statement allegedly here by Mr. Stewart [from the May 16 conference call] that says, "Despite the changes caused by recent events the management team remains confident that we have the resources and the skill to build CollaGenex into a broadly based speciality pharmaceutical company which sustains the focus of the vision we have been promoting for the last 18 months and this remains our focus. We believe that we will be successful." Now he says there is some doubt to that. There is no doubt expressed here.

Plaintiffs' Counsel: What resources were you referring to there, Mr. Stewart?

Stewart: The resources that we have with R and D, and the resources we have with the management.

(Tr. 45-46.) Therefore, Plaintiffs ask the Court to believe that CollaGenex did not contemplate the feasibility or likelihood of FDA approval when it made the statement, "we have the resources and the skill to build CollaGenex into a broadly based speciality pharmaceutical company." Plaintiffs appear to be arguing both that the viability of CollaGenex as a whole is threatened, and that the viability of CollaGenex's dental business is threatened even though, in its earlier filings, Plaintiffs focused on the viability of CollaGenex as a whole. Only after being called upon by Defendants, and then this Court, to reconcile the statements do Plaintiffs argue both theories with

only the slightest acknowledgment that the statements made in the original moving papers were overstatements. (Tr. 42-44)

In short, Plaintiffs argue (both then and now) that CollaGenex, as a whole, will be irreparably harmed, and that it is unsure whether it will be unable to cultivate its dermatological practice. Additionally, Plaintiffs now argue that loss of its dental practice alone constitutes irreparable harm.

To its shareholders and the public, Plaintiffs paint an optimistic picture of its potentially Periostat®-less future. To the Court, CollaGenex will "try" to "hopefully" recover from generic competition for Periostat® and "there is a chance" they will be profitable. (Tr. 15, 46) To the Court, "exciting" means unpleasant, perhaps catastrophic, and "calls to mind the old curse," while shareholders are told that CollaGenex "expect[s] to do really well in the future." (Tr. 43.) And, in its May 5 conference call, Stewart stated CollaGenex was "well prepare[d] for an eventual entry [of generic competition] and remain very focused on the significant opportunity that lies ahead in dermatology." (Tr. 3.) Though Plaintiffs have presented evidence of layoffs and discontinuances in relation to its dental market, it has failed to satisfactorily reconcile the statements about its dermatological endeavors given to this Court with those given in the May 5 conference call and Annual Letter, leading this Court to believe that Plaintiffs have been less than candid in its submissions hereto.

As a result, the Court is not persuaded that irreparable harm will result if CollaGenex continues, as planned, to develop its presence in the market for dermatological pharmaceuticals. The evidence and testimony presented, in conjunction with the relevant precedent of ***Eli Lilly***,

compel the Court to agree with Judge Pohorelsky in finding that the significance of the harms that CollaGenex alleges it will suffer are not compelling:

> Lilly contends that the loss of profits on sales...because of competition...will result in irreparable injury to Lilly's overall pharmaceutical research efforts...[T]hat claim of injury is not materially different from any claim of injury by a business that is deprived of funds that it could usefully reinvest. If a claim of lost opportunity to conduct research were sufficient to compel a finding of irreparable harm, it is hard to imagine any manufacturer with a research and development program that could not make the same claim and thus be equally entitled to preliminary injunctive relief. Such a rule would convert the 'extraordinary' relief of a preliminary injunction into a standby remedy, available whenever the plaintiff has shown likelihood of success on the merits. For that reasons, adopting the principle that Lilly proposes would 'disservice the patent system.'

82 F.3d at 1578. Plaintiffs distinguished *Eli Lilly* solely on the ground that it is a large company for which "loss of one revenue generating product...has almost no impact." (Objection at 9 n.11.) However, the court in *Eli Lilly* did not condition the applicability of the principles of patent law on the size of the company. It cautioned against finding irreparable harm based on factors that are likely to be present in any patent case.

Other Objections

In Plaintiffs' Objections, they also argued that "[i]t [was] legal error to ignore precedent and not weigh evidence of the irreparable harm CollaGenex will suffer." In arguing that a plaintiff holding a patent on which little time remains has shown irreparable harm, Plaintiffs again cite only to cases in which the party requesting the injunction has shown a likelihood of success on the merits, triggering a presumption of irreparable harm that Plaintiffs have not earned in this case. *See* *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451-7 (Fed. Cir. 1988) (affirming injunction where, *inter alia*, district court found irreparable harm based on nine

factors and plaintiff showed likelihood of success on the merits of validity of patent and patent infringement); *Pharmacia & Upjohn Co v. Ranbaxy Pharm., Inc.*, 274 F. Supp. 2d 597, 614 (D. N.J. 2003) (injunction granted where presumption of irreparable harm given to plaintiff and, *inter alia*, damages speculative, potential for significant damage award if defendant found liable and difficulty pursuing collection overseas considered); *Ortho Pharm. Corp. v. Smith*, 1990 WL 18681, *9, 15 U.S.P.Q.2d 1856 (E.D. Pa. Feb. 23, 1990) (granting defendant's motion for preliminary injunction where defendant showed likelihood of success on the merits, irreparable harm presumed and court looked to "several factors which *add* too the irreparable harm") (emphasis added).

Indeed, many of the cases cited by Plaintiffs in support of their argument that they have established irreparable harm are ones in which the plaintiff has the presumption of irreparable harm either (A) based on an earlier showing of likelihood of success on the merits and/or (B) are appeals, in which the court evaluates whether the district court committed an abuse of discretion, factors that significantly change the persuasiveness of those cases. *See*, *e.g.*, *Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001). In *Purdue Pharma*, a case Plaintiffs cite for the proposition that price erosion is sufficient to show irreparable harm, the plaintiff made a "clear" showing of likelihood of success on the merits, was given the presumption of irreparable harm, which, in turn, placed the burden on the defendant to show the plaintiff would not be irreparably harmed. *Id.* at 1367-8. Defendant argued that the testimony of plaintiffs' expert regarding price erosion and market position was speculative. *Id.* "Given the testimony of the likelihood of price erosion and loss of market position without corresponding market expansion from [defendant's] product, [the court] saw no deficiency in the district court's

finding of irreparable harm." *Id.* at 1368. This is not the same, as Plaintiffs here argue, as finding "price erosion sufficient." Plaintiffs here have neither the presumption of irreparable harm nor the standard of review in their favor and without either, the isolated factors to which it points are not persuasive, particularly in light of the evidence discussed and presented at the May 23 oral argument that seriously undercuts Plaintiffs' argument that CollaGenex's viability is at skate.

Similarly, the persuasiveness of *Bio-Technology v. Genentech*, 80 F.3d 1553, 1565-6 (Fed. Cir. 1996) (cited by Plaintiffs in support of their argument that loss of research and development is sufficient to constitute irreparable harm), is also severely mitigated by its posture. There, the Court first acknowledged that the nonmoving party failed to rebut the presumption of irreparable harm. *Id.* The court then went on: "*In addition* [to the presumption of irreparable harm], the district court determined that Genentech would be harmed if BTG were allowed to enter the market because Genentech would lose revenues and good will and would be required to reduce its research and development activities." *Id.* at 1566 (emphasis added). It did not hold that loss of research and development were sufficient to establish irreparable harm. *See also Hybritech*, 849 F.2d at1456; *Atlas*, 773 F.2d 1230 (finding defendant's argument that the availability of money damages precluded injunction insufficient to show abuse of discretion of district court).

The cases cited by Plaintiffs that are distinguishable on significant grounds are many. Plaintiffs cite inapposite cases for their statement that "loss of business opportunity...is as significant...as substantial loss profits." *Compare* Objection at 7 *with Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc.*, 134 F.3d 1085, 1090 (Fed. Cir. 1988) (no clear error by district court

where plaintiff entitled to presumption of irreparable harm and defendant failed to rebut that presumption due to nature of patent and loss of market share); *and* Cordis Corp. v. Medtronic, Inc., 835 F.2d 859, 864 (Fed. Cir. 1987) (affirming grant of injunction and finding pacemaker industry in particular to be "highly competitive" based on precedent indicating that irreparable harm likely without injunction). Neither case equates loss of business opportunity with substantial lost profits.

Plaintiffs are correct that loss of a business needn't be total "so long as it is so great as to seriously compromise the company's ability to continue in its current form." Galvin v. New York Racing Assoc., 70 F. Supp. 2d 163, 170 (E.D.N.Y. 1988) (Ross, J.). However, Galvin involved a professional equine thoroughbred racehorse veterinarian who sought an injunction to continue practicing during the pendency of investigations. Id. at 168. Without the injunction, the plaintiff would not have been able to practice in any of defendant's establishments, leaving him without an opportunity to practice his trade in the New York area. CollaGenex does not face a similar fate. Its lot is more comparable to the plaintiff in P.J. Grady, Inc. v. General Motors Corp., 472 F. Supp. 35, 37 (E.D.N.Y. 1979) (no irreparable harm where defendant terminated Buick dealership and plaintiff also maintained Chevrolet dealership), than the plaintiffs in cases where the one item sold by a plaintiff is taken away. See generally Roso-Lino Beverages Distrib., Inc. v. Coca-Cola Bottling Co. of New York, 749 F.2d 124 (2d Cir. 1984) (irreparable harm where Coca-Coca bottler had no other products); Semmes Motors, Inc. v. Ford Motor Co., 429 F.2d 1197, 1205 (2d Cir. 1970) (irreparable harm where arrangement terminated, leaving Ford-only company without any vehicles for sale). For these same reasons, CollaGenex's argument that it is a "one-product" company is also unpersuasive. Though the Court acknowledges that, in 2004,

Periostat® was source of a 80% of Plaintiffs' revenues, there is substantial evidence to indicate that there is more than one successful product in CollaGenex's portfolio.

SUNY Plaintiff

Additionally, Plaintiffs' argument that loss of licensing revenues to SUNY will result in irreparable harm is without merit. *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995) (grant of license shows that owner "is willing to forego its patent rights for compensation").

DC Action

The decision in *CollaGenex Pharmaceuticals v. Thompson*, 2003 WL 21697344 (D.D.C. Aug. 6, 2003) is not binding on this Court. However, Plaintiffs ask that the Court find irreparable harm because Judge Collyer found irreparable harm when considering the impact had the Food and Drug Administration ("FDA") approved a generic version of Periostat® at that time. However, not only did Judge Collyer, in a subsequent opinion, dismiss Plaintiffs' complaint and dissolve the injunction, 2005 WL 256561, *1 (D.D.C. Jan.19, 2005), but, the United States Court of Appeals for the District of Columbia denied Plaintiffs' emergency petition for injunctive relief pending appeal for failure to meet the "stringent standards required for injunctive relief." 2005 U.S. LEXIS 1520 (D.C. Cir. 2005).

In light of the foregoing, this Court agrees with Judge Pohorelsky's finding that, of the host of harms Plaintiffs claim they will suffer, "most...emanate from an expected sharp drop in revenue" which can be quantified and, without the presumption of irreparable harm that accompanies the court's finding of likelihood of success on the merits, the harms alleged are insufficient to warrant an injunction. The Court also agrees with Judge Pohorelsky that any

harm caused by Plaintiffs' agreement with Mutual is harm that was bargained-for and not proper for consideration of the instant motion. Furthermore, it is significant that CollaGenex stopped supporting Periostat® before a decision on whether a preliminary injunction would issue and has no intention of attempting to compete with the generic version of Periostat®, but appears to prefer shutting down that portion of its business.[2] For these reasons, the Court finds that Plaintiffs have not made a showing of irreparable harm sufficient to warrant either a preliminary injunction or a temporary restraining order.

[2] Stewart testified that Plaintiffs' decision to stop supporting Periostat® was voluntary; that no effort was made to consider whether CollaGenex could lower prices and compete with other companies; and that CollaGenex wanted there to be no generic competition. (Tr. 39.)

CONCLUSION

After reviewing Magistrate Judge Pohorelsky's Report and Recommendation and Plaintiffs' Objections thereto, the Court adopts and affirms the Report and Recommendation. Plaintiffs' motions for a temporary restraining order and preliminary injunctive relief are denied.

SO ORDERED.

S/
SANDRA L. TOWNES
UNITED STATES DISTRICT JUDGE

Dated: June 15, 2005
Brooklyn, NY